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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,979	05/10/2000	THOMAS J. HIGGINS	33-00	4903
23713	7590	01/30/2004	EXAMINER	
GREENLEE WINNER AND SULLIVAN P C 5370 MANHATTAN CIRCLE SUITE 201 BOULDER, CO 80303			COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Applicati n No.

09/508,979

Applicant(s)

HIGGINS ET AL.

Examin r

Cynthia Collins

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2003 and 14 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1,2,4-6,8,11-57,64,65,67-69,86-94 and 96-115 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8,11-57,64,65,67-69,86-94 and 96-115 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The Amendments filed July 29, 2003 and November 14, 2003 have been entered.

Claims 3, 7, 9, 10, 58-63, 66, 70-85 and 95 are cancelled.

Claims 1, 15, 17, 21, 28, 33, 38, 47, 52, 56, 57, 64, 65, 88 and 101 were amended in the response filed July 29, 2003.

Claims 33 and 42 were amended in the response filed November 14, 2003.

Claims 102-115 were newly added in the response filed July 29, 2003.

Claims 1-2, 4-6, 8, 11-57, 64-65, 67-69, 86-94 and 96-115 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### ***Claim Rejections - 35 USC § 112***

Claims 110-115 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 110-115 are directed to the method according to claim 1 in which the total protein nitrogen content of the storage organ of the plant is increased by at least 10%, the total amino acid composition of the storage organ of the plant is increased by at least 8%, the total fiber content of the storage organ of the plant is increased by at least 5%, the total starch content of the

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storage organ of the plant is increased by at least 10%, the total fatty acid content of the storage organ of the plant is increased by at least 5%, and the content of any one fatty acid in the storage organ of the plant is increased or decreased by at least 5%. The recited limitations do not find support in the specification as originally filed, and thus constitute new matter.

Claims 1-2, 4-6, 8, 11-57, 64-65, 67-69 and 86-94 and 96-101 remain rejected, and claims 97-115 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing the total protein nitrogen content in the seed of a pea, chickpea or rice plant, said method comprising (i) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin operably linked to a promoter sequence capable of conferring expression in a seed, and (ii) determining the content of total protein nitrogen in said seed, a method of increasing the fiber content in the seed of a pea plant, said method comprising (i) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the content of fiber in said seed, a method of decreasing the fiber content, decreasing the soluble and insoluble non-starch polysaccharide components of fiber, and increasing the lignin component of fiber, in the seed of lupin a plant, said method comprising (i) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the content or composition of fiber in said seed, a method of increasing the oil content, and increasing the stearic acid and oleic acid fatty acid components of oil, and decreasing the myristic acid, palmitic acid, linoleic acid, linolenic acid, arachidic acid, gadoleic acid, behenic acid, erucic acid and lignoceric acid fatty acid components of oil, in the seed of lupin a plant, said method comprising

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(i) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the content of oil in or the fatty acid composition of said seed, a method of decreasing the oil and starch content in the seed of a pea plant, said method comprising (i) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the content of oil or starch in said seed, a method of increasing the amino acids aspartic acid, threonine, serine, glutamic acid, proline, glycine, alanine, valine, isoleucine, leucine, arginine, cysteine and methionine in the seed of a pea plant, said method comprising (i) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the amino acid composition of said seed, and a method of increasing the amino acids aspartic acid, threonine, serine, glutamic acid, proline, glycine, alanine, valine, isoleucine, leucine, arginine, cysteine, methionine, tyrosine, phenylalanine and lysine in the seed of a chickpea plant, said method comprising (i) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the amino acid composition of said seed, does not reasonably provide enablement for methods of modifying the content or composition of any metabolite in any storage organ of any plant by expressing in the storage organ a chimeric gene comprising a nucleotide sequence encoding any sulfur-rich protein operably linked to any promoter, for the reasons of record set forth in the office action mailed January 29, 2003.

Applicant's arguments filed July 29, 2003 have been fully considered but they are not persuasive.

Applicant argues that since the level of skill in the art of plant molecular biology is high, since the 2S family of proteins is known in the art, and since transcriptional regulatory sequences

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for directing expression in target organs are also known in the art, one of ordinary skill in the art could use known sequences in readily available vectors for the genetic modification of a plant without undue experimentation (reply page 21).

While it is not disputed that the level of skill in the art of plant molecular biology is high, or that the 2S family of proteins is known in the art, or that transcriptional regulatory sequences for directing expression in target organs are also known in the art, the Examiner maintains that it would require undue experimentation for one of ordinary skill in the art to practice the invention as claimed. The claimed invention is not limited to using known sequences in readily available vectors for the genetic modification of plants. The claimed invention is directed to using known sequences in readily available vectors for the genetic modification of any plant in order to obtain plants in which the content or composition of fatty acid, starch, soluble non-starch polysaccharide, insoluble non-starch polysaccharide, fiber or total protein nitrogen in any unspecified storage organ of the plant is modified in any unspecified manner. In contrast, the specification provides guidance for using one sequence (encoding sunflower seed albumin) for the genetic modification of lupin, pea, chickpea and rice plants to produce plants in which the content or composition of fatty acid, starch, soluble non-starch polysaccharide, insoluble non-starch polysaccharide, fiber or total protein nitrogen in seeds of the plant is modified in a specific manner, depending on the plant species transformed. The specification does not provide guidance with respect to how to use other known sequences to specifically modify the content or composition of the recited metabolites in a plant storage organ. The specification also does not provide guidance with respect to how to use known sequences to specifically modify the content or composition of the recited metabolites in storage organs other than seeds, or in plants species

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other than those exemplified. Such guidance is necessary for enablement because the ability of a nucleotide sequence encoding any sulfur-rich protein from any source, including any 2S protein or the Asp1 synthetic protein, to modify the content or composition of any metabolite, including fatty acid, starch, non-starch polysaccharide, insoluble non-starch polysaccharide, fiber and total protein nitrogen, in any storage organ of any species of transgenic plant is unpredictable.

Claims 1, 6, 28, 33, 42, 47, 52, 89, 91, 94 and 101 remain rejected, and claims 102, 104, 105, 107, 108 and 109 are rejected, under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “modifying” and “modified”, for the reasons of record set forth in the office action mailed January 29, 2003.

Applicant's arguments filed July 29, 2003 have been fully considered but they are not persuasive.

Applicant argues that the specification provides various examples of changes that are modifications, and that such changes would be understood in the art as modifications (reply page 22).

The rejection is maintained because the examples set forth in the specification do not limit the terms “modifying” and “modified” set forth in the rejected claims. Furthermore, that the various examples set forth could be understood as modifications does not limit the terms “modifying” and “modified” set forth in the rejected claims. The claims encompass any and all modifications in the content or composition of any metabolite in any storage organ of any plant, yet the specification discloses only specific types of changes in the content or composition of specific metabolites in the seeds of specific plants. Additionally, newly rejected claims 102, 104,

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105, 107, 108 and 109 do not recite any comparative basis for the relative terms “modifying” and “modified”.

Claim 65 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the use of parentheses in line 6. The use of parentheses makes it unclear whether joba and common bean are meant to be claim limitations.

Claim 103 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “increasing”. “Increasing” is a relative term lacking a comparative basis.

Claim 106 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “decreasing”. “Decreasing” is a relative term lacking a comparative basis.

Claim 111 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “increased by at least 8%” in reference to “the total amino acid composition”. It is unclear how any composition could increase, as “composition” refers to amino acid ratios, which may change, but would not increase or decrease.

***Claim Rejections - 35 USC § 102***

Claims 42-44 and 64 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Molvig et al. (August 1997, Proc. Natl.



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Acad. Sci. USA, Vol. 94, pages 8393-8398, Applicant's IDS), for the reasons of record set forth in the office action mailed January 29, 2003.

Applicant's arguments filed July 29, 2003 have been fully considered but they are not persuasive with respect to the claims for which the rejection is maintained.

Applicant argues that Molvig et al. contains no disclosure or teaching relevant to the modification of fatty acid, starch, soluble non-starch polysaccharide, insoluble non-starch polysaccharide, fiber and total protein nitrogen as recited for example in claim 1. Applicant also argues that the claimed invention does not clearly follow from the teachings of Molvig et al., as Molvig et al. does not disclose or teach the step of selecting a plant having a modified content and or composition of the recited metabolites, or plants other than lupins. Applicant further argues that the claim limitations with respect to metabolites other than amino acids are not certain characteristics or properties claimed, but specific recitals of modification of specific metabolites and specific method steps (reply pages 23-24).

While Molvig et al. does not teach that their disclosed method modifies fatty acid, starch, soluble non-starch polysaccharide, insoluble non-starch polysaccharide, fiber, or total protein nitrogen, Molvig et al. need not explicitly teach such an end result to anticipate the currently rejected claims, as the currently rejected claims are limited to those in which such modifications would merely be an end result of practicing the affirmative method steps set forth in the rejected claims and explicitly taught by Molvig et al., namely the expression in seeds of a gene encoding sunflower seed albumin followed by the determination of the amino acid composition of seeds. Furthermore, the currently rejected claims are limited to those directed to plants or dicotyledonous plants generically.

Claims 65 and 67-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Altenbach et al. (Plant Mol Biol. 1992 Jan; 18(2): 235-45, Applicant's IDS).

The claims are drawn to a transgenic oilseed rape plant expressing in a storage organ a chimeric gene comprising a nucleotide sequence encoding a 2S protein, said sequence operably linked to a promoter capable of conferring expression in a storage organ.

Altenbach et al. teach transgenic oilseed rape plants expressing in a seed a chimeric gene comprising a nucleotide sequence encoding the brazil nut albumin 2S protein, said sequence operably linked to a promoter capable of conferring expression in a seed (page 238 Figure 1).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794.

The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
January 22, 2004

*Amy Nelson for*  
Elizabeth McElwain

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